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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,309	08/27/2001	Virginia Pact Richter	4164-101 CON	5504

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,309	RICHTER ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 3, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *15 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16 and 18-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

An Amendment filed November 3, 2003 is acknowledged. Claims 1-14, 16 and 18-30 remain under consideration wherein mirtazapine, the elected species, appears to be free of the prior art. Claims 15 and 17 remain withdrawn from consideration as being drawn to non-elected inventions.

An Information Disclosure Statement filed August 27, 2001 is further acknowledged and has been reviewed.

The filing of a Terminal Disclaimer, in response to the rejection of claims 1-14, 16 and 18-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent 6,281,207, is acknowledged. This rejection of record is withdrawn.

Claims 1-14, 16, 18, 23, 24, 26-28 and 30 are rejected under judicially created doctrine as being drawn to an improper Markush group. The members of a proper Markush group must share a common utility as well as a substantial structural feature disclosed as being essential to that utility. Lack of unity of invention has been found to exist since a common nucleus among the various disclosed 5HT antagonists and $\alpha 2$ antagonists is absent. A prior art reference anticipating the claims under 35 U.S.C. 102 with respect to one species, for example, mirtazapine, would not render the same claims obvious under 35 U.S.C. 103 with respect to another species, as an ergot alkaloid. The members of the instant Markush group possess widely different properties and are not considered functionally equivalent.

Deletion of the non-elected subject matter would resolve the issue.

The claims will be examined fully with respect to the elected species only and further to the extent necessary to determine patentability. See MPEP 802.03.

Claims 1-14 and 18, 23, 24, 26-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way a to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. There is no reference to compound 5-MDOT in the specification. In re Rasmussen, 211 USPQ 323. Applicants may wish to state where in the specification this compound finds support.

Claims 3 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitations in claims 3 and 16, respectively, "including at least one..." and "including a therapeutic agent ..." render the claims indefinite. The metes and bounds of the claimed compositions cannot be precisely determined. Clarification is required.

Claims 1-4, 6-12, 26, 27 and 30 were rejected in the last Office Action under 35 U.S.C. 102(b) as being anticipated by Henry et al., Experimental Neurology. It was asserted Henry teaches the administration of the 5-HT uptake inhibitor, 5-MDOT, to combat the movement disorder dyskinesias that are associated with Parkinson's disease. Because the present specification fails to include 5-MDOT specifically, the rejection is maintained over claims 1-3, 6-12, 26, 27 and 30. The rejection is presently extended to claim 13.

In the last Office Action a rejection under both 35 U.S.C. 102(b) and 35 U.S.C. 103 relied upon the reference Rawlow et al., European Journal of Pharmacology. Following the present exclusion of cyproheptadine, both rejections of record are withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 6-14, 16, 18, 23-28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin-Shiau et al., Pharmacol., Biochem. Behav., (abstract).

Lin-Shiau teaches the administration of mianserin, methysergide or metergoline to ameliorate tremors in a laboratory setting.

Claims 1-14, 16 and 18-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to combating any movement disorder comprising administering a 5HT antagonist and/or α_2 antagonist. The specification provides support for the treatment of Parkinson's disease comprising administering mirtazapine.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treatment of many types of movement disorders comprising administering any of a number of compounds that are characterized as 5HT antagonists and/or α_2 antagonists.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the field of neurology.

Each particular movement disorder has its own specific characteristics and etiology. The unpredictability observed with single agent therapy is compounded when a combination of agents is employed. The broad recitation "combating a movement disorder is inclusive of many conditions that presently have no established successful therapies.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any movement disorder outside the scope of Parkinson's disease comprising administering a plethora of structurally distinct compounds.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of mirtazapine in the treatment of movement disorders. There is no support for the subject matter of claim 24 wherein the administered composition does not mediate sedation.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular 5HT antagonist and/or $\alpha 2$ antagonist would be preferred for treatment of a particular type of movement disorder. The skilled artisan would expect the interaction of a particular drug, or combination of drugs, in combating a particular movement disorder to be very specific

and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding nor any criteria for extrapolating beyond the administration of mirtazapine in defined pathological states. Even for the Examples set forth, no direction is provided to administer any other neurotransmission modulating composition other mirtazapine. Absent reasonable *a priori* expectations of success for using a particular antagonist to treat any particular movement disorder, one skilled in the neurology art would have to test extensively many agents to discover which particular disorder responds to that particular agent. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 517-272-0585.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

February 28, 2004

PHYLLIS SPIVACK
PRIMARY EXAMINER